

# **EXHIBIT I**

Paul J. Michaels, M.D.

Page 1

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC	)	Master File No.
REPAIR SYSTEM PRODUCTS	)	
PRODUCTS LIABILITY LITIGATION	)	2:12-MD-02327
	)	
THIS DOCUMENT RELATES TO THE	)	MDL 2327
FOLLOWING CASES IN WAVE 2	)	
OF MDL 200:	)	
	)	JOSEPH R. GOODWIN
Tamara Carter, et al. v.	)	
Ethicon, Inc., et al.	)	U.S. DISTRICT JUDGE
Civil Action No. 2:12-cv-01661	)	
	)	
Sandra Childress, et al. v.	)	
Ethicon, Inc., et al.	)	
Civil Action No. 2:12-cv-01564	)	
	)	
Marion Chrysler v.	)	PAUL J. MICHAELS, M.D.
Ethicon, Inc., et al.	)	
Civil Action No. 2:12-cv-02060	)	JUNE 18, 2016
	)	
Melissa Sanders, et al. v.	)	
Ethicon, Inc., et al.	)	
Civil Action No. 2:12-cv-01562	)	
	)	
Ana Sierra, et al. v.	)	
Ethicon, Inc., et al.	)	
Civil Action No. 2:12-cv-01819	)	
	)	
Toni Hernandez v.	)	
Ethicon, Inc., et al.	)	
Civil Action No. 2:12-cv-02073	)	
	)	

Reported by:

Rebecca J. Callow, RMR, CRR, RPR

## Paul J. Michaels, M.D.

<p style="text-align: right;">Page 2</p> <p>1 2 3 DEPOSITION OF PAUL J. MICHAELS, M.D. 4 THIS DOCUMENT RELATES TO MARION CHRYSLER 5 Austin, Texas 6 Saturday, June 18th, 2016 7 4:18 p.m. 8 9 10 Deposition of PAUL J. MICHAELS, M.D, pursuant to 11 Notice held at the offices of Hissey Kientz, 12 9442 N. Capital of Texas Highway Building 1, 13 First Floor Conference Room, Austin, Texas, before 14 Rebecca J. Callow, Registered Merit Reporter, 15 Certified Realtime Reporter, Registered 16 Professional Reporter, and Notary Public in and 17 for the State of Texas. 18 19 20 21 22 23 24</p>	<p style="text-align: right;">Page 4</p> <p>1 A P P E A R A N C E S: 2 3 FOR JOHNSON &amp; JOHNSON AND ETHICON, INC.: 4 Thomas Combs &amp; Spann PLLC 5 300 Summers Street 6 Suite 1380 7 Charleston, West Virginia 25301 8 (304) 414-1807 9 BY: David B. Thomas, Esquire 10 dthomas@tcspllc.com 11 12 FOR JOHNSON &amp; JOHNSON AND ETHICON, INC.: 13 Butler Snow, LLP 14 150 3rd Avenue South 15 Suite 1600 16 Nashville Tennessee 37201 17 (615) 651-6700 18 BY: M. Andrew Snowden, Esquire 19 andy.snowden@butlersnow.com 20 21 22 23 24</p>
<p style="text-align: right;">Page 3</p> <p>1 A P P E A R A N C E S: 2 3 FOR PLAINTIFFS: 4 Aylstock, Witkin, Kreis &amp; Overholtz, PLLC 5 17 East Main Street 6 Suite 200 7 Pensacola, Florida 32502 8 (850) 202-1010 9 BY: Bryan F. Aylstock, Esquire 10 baylstock@awkolaw.com 11 12 FOR PLAINTIFFS: 13 Danny L. Curtis, P.C. 14 9229 Ward Parkway 15 Suite 370 16 Kansas City, Missouri 64114 17 (816) 523-4667 18 BY: Danny L. Curtis, Esquire 19 dcurtis@dannylcurtispc.com 20 21 22 23 24</p>	<p style="text-align: right;">Page 5</p> <p>1 INDEX 2 PAGE 3 PAUL J. MICHAELS, M.D. 4 Examination by Mr. Snowden .....6 5 Changes and corrections .....57 6 Signature Page .....58 7 Court Reporter's Certificate .....59 8 9 10 11 12 EXHIBITS 13 NO. DESCRIPTION PAGE 14 Exhibit 1 Expert Report of Paul J. 6 15 Michaels. M.D. (Re: Marion 16 Chrysler) 17 Exhibit 2 4/18/2013 Surgical Pathology 37 18 Report for Marion Chrysler 19 20 21 22 23 24</p>

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<p style="text-align: right;">Page 6</p> <p>1 (Exhibit 1 marked.)</p> <p>2 PAUL J. MICHAELS, M.D.,</p> <p>3 Called as a witness herein, having been first duly</p> <p>4 sworn by a Notary Public, was examined and testified as</p> <p>5 follows:</p> <p>6 EXAMINATION</p> <p>7 BY MR. SNOWDEN:</p> <p>8 Q. Good afternoon, Dr. Michaels.</p> <p>9 A. Good afternoon.</p> <p>10 Q. I'm handing you what's been marked as</p> <p>11 Exhibit 1. Could you take a look at that, please,</p> <p>12 and let me know if that contains your entire</p> <p>13 case-specific report regarding Marion Chrysler.</p> <p>14 (Document review.)</p> <p>15 A. Yes.</p> <p>16 BY MR. SNOWDEN:</p> <p>17 Q. Okay. And does that Exhibit No. 1 contain</p> <p>18 all of your case-specific opinions regarding</p> <p>19 Ms. Chrysler?</p> <p>20 A. Yes.</p> <p>21 Q. Have you done any work since the date you</p> <p>22 signed this report on Ms. Chrysler's case?</p> <p>23 A. Yes.</p> <p>24 Q. And what have you done?</p>	<p style="text-align: right;">Page 8</p> <p>1 records?</p> <p>2 A. I would have to go through my computer</p> <p>3 where I have all of them and confirm, but I reviewed</p> <p>4 extensive diverse medical records. So I would</p> <p>5 imagine that that's a complete and accurate list.</p> <p>6 Q. How many mesh specimens did you review for</p> <p>7 Ms. Chrysler?</p> <p>8 A. Just one.</p> <p>9 Q. And did that come to you already prepared</p> <p>10 on histology slides?</p> <p>11 A. Yes.</p> <p>12 Q. So you haven't reviewed a gross specimen</p> <p>13 for Ms. Chrysler?</p> <p>14 A. Correct.</p> <p>15 Q. Beginning on page 4 of your report in the</p> <p>16 section in all caps, "Marion Chrysler," is that sort</p> <p>17 of your summary of -- well, let me just ask it.</p> <p>18 What's the purpose of this section of</p> <p>19 your report?</p> <p>20 A. It's a brief summary of my review of her</p> <p>21 pertinent medical history and course.</p> <p>22 Q. And how do you decide what's included in</p> <p>23 this summary?</p> <p>24 A. It's what I determine as a physician is</p>
<p style="text-align: right;">Page 7</p> <p>1 A. I reviewed her deposition, and I</p> <p>2 re-reviewed her medical records. And I reviewed the</p> <p>3 defense pathology expert report. I would say that's</p> <p>4 about it.</p> <p>5 Q. Okay. And based on that work that you've</p> <p>6 done, is there anything you want to change about</p> <p>7 your opinions in this case?</p> <p>8 A. No.</p> <p>9 Q. Okay. Do you have any changes at all to</p> <p>10 your opinion before we start?</p> <p>11 A. Not that I know of.</p> <p>12 Q. If you turn to the last page of the</p> <p>13 exhibit.</p> <p>14 A. Okay.</p> <p>15 Q. There's a list there of materials reviewed.</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. It lists the deposition of Sean Ryan.</p> <p>19 Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. You didn't review that one?</p> <p>22 A. I don't recall reviewing that, no.</p> <p>23 Q. And in terms of the medical records you see</p> <p>24 listed below, have you reviewed all those medical</p>	<p style="text-align: right;">Page 9</p> <p>1 medically relevant.</p> <p>2 Q. And if you go -- if you start at the</p> <p>3 beginning, it lists her past medical history in the</p> <p>4 third sentence.</p> <p>5 Do you see where I am?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. And do you see polycystic kidney</p> <p>8 disease?</p> <p>9 A. Yes.</p> <p>10 Q. What impact, if any, did that have on your</p> <p>11 opinions in this case?</p> <p>12 A. Well, patients with polycystic kidney</p> <p>13 disease can have recurrent urinary tract infections.</p> <p>14 They can have a lot of renal functional issues</p> <p>15 requiring transplant, because the parenchyma of the</p> <p>16 kidneys is basically fibrotic because of the</p> <p>17 numerous cysts that they develop microscopically and</p> <p>18 become apparent grossly. I would say that would be</p> <p>19 the main issues of polycystic kidney disease.</p> <p>20 Q. Can it be painful?</p> <p>21 A. They can.</p> <p>22 Q. Do you know whether Ms. Chrysler's</p> <p>23 polycystic kidney disease caused her pain?</p> <p>24 A. I don't recall reading if she experienced</p>

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<p style="text-align: right;">Page 10</p> <p>1 any sort of dull, aching abdominal pain with her 2 polycystic kidney disease -- that was attributed to 3 her polycystic kidney disease. 4 But it seemed to me, based on the 5 reports of pain that I read, that the quality and 6 timing of the pain was not consistent with it being 7 from her polycystic kidneys. 8 Q. Will you be offering any opinions in this 9 case regarding urinary symptoms experienced by 10 Ms. Chrysler? 11 A. As in like her infections? I don't know 12 what urinary symptoms you're referring to. 13 Q. Well, are there any urinary symptoms that 14 you will -- that you're attributing to the mesh in 15 this case? 16 (Document review.) 17 A. Other than the erosion through her urethra 18 and the pain associated with that, no. 19 BY MR. SNOWDEN: 20 Q. Will you be offering any opinions in this 21 case that the mesh implanted in Ms. Chrysler was 22 cytotoxic? 23 A. I do not know what you mean by "cytotoxic." 24 Like, I'm not used to hearing "cytotoxic" in the</p>	<p style="text-align: right;">Page 12</p> <p>1 under the protocol. So if you'd like to send us 2 those, we'll make a blanket request right now and -- 3 MR. SNOWDEN: Okay. And just for the 4 record, that's the first request I've received 5 related to it. 6 MR. AYLSTOCK: Oh, well, no. You've 7 received blanket requests and opposed them every 8 single time. I myself have sent you them, so I 9 disagree with your characterization. 10 MR. SNOWDEN: All right. Bryan, 11 you're welcome to re-send me that e-mail, or 12 wherever you've made that request, and I'll look at 13 it. But can we continue with the deposition? 14 MR. CURTIS: Go ahead. 15 MR. SNOWDEN: Did I get an answer to 16 the last question? I don't think I did. And if I 17 didn't, would you please re-read it. 18 (The record was read as requested: 19 "Are you offering any opinions at 20 trial that -- regarding any loose 21 polypropylene particles within 22 Ms. Chrysler's tissue?") 23 MR. CURTIS: Subject to my objection. 24 A. I will have to, I guess, wait until trial</p>
<p style="text-align: right;">Page 11</p> <p>1 description of a foreign body. 2 Q. Will you be offering any opinions in this 3 case that the polypropylene used in Ms. Chrysler's 4 TVT posed a risk of cancer for her? 5 A. No. 6 Q. Will you be offering an opinion in this 7 case regarding any loose particles out in the tissue 8 from Ms. Chrysler's TVT? 9 A. I don't specifically know of loose tissues 10 that I've read about in her medical records. 11 Q. And I'm sorry. My question wasn't clear. 12 It probably was -- it's getting late. 13 Do I -- are you offering any opinions 14 at trial that -- regarding any loose polypropylene 15 particles within Ms. Chrysler's tissue? 16 MR. CURTIS: I object to the form of 17 the question. I mean, he doesn't really know what 18 opinions he's going to be -- he can tell you what 19 opinions he has today, but he doesn't know what he's 20 going to be asked to do at trial. So I think maybe 21 you can ask him what opinions he's formed. 22 MR. AYLSTOCK: So the record's clear 23 as well, we'd love to have every pathology slide 24 that your experts were provided for every division</p>	<p style="text-align: right;">Page 13</p> <p>1 to see what I'm asked, because I -- if I'm 2 comfortable answering a question, whether it's in a 3 deposition or at trial, based on the information in 4 the data that I have at hand, I'll answer it. 5 So with regards to cancer and 6 cytotoxic effects of the mesh, I don't know of 7 anything about that. So I would say comfortably, 8 more likely than not, I wouldn't be offering any of 9 those opinions at trial. 10 But if I'm made aware of other medical 11 records or other slides that are out there that 12 demonstrate fragments of mesh that are not 13 associated -- you know, loose fragments of mesh not 14 associated with the main mesh material that are out 15 in the tissue, then, yes, I could change my -- or 16 amend my opinion at a later time. 17 BY MR. SNOWDEN: 18 Q. As you sit here today, do you have an 19 opinion regarding any loose particles of 20 polypropylene in Ms. Chrysler's specimen? 21 A. As I sit here today, I do not have any 22 specific opinion regarding loose mesh particles 23 within Ms. Chrysler. 24 Q. Do you have any opinions that the TVT sheds</p>

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<p style="text-align: right;">Page 14</p> <p>1 particles?</p> <p>2 MR. AYLSTOCK: We're getting very</p> <p>3 general. I'm not going to tell him not to answer,</p> <p>4 but this is an example of something that is clearly</p> <p>5 a general question. He's already said he's -- what</p> <p>6 he's going to testify to here, and now you ask a</p> <p>7 general question.</p> <p>8 A. Can I answer?</p> <p>9 BY MR. SNOWDEN:</p> <p>10 Q. Yes.</p> <p>11 A. With respect to this case, I don't know of</p> <p>12 anything mentioned in the medical records that</p> <p>13 specifically addressed disrupted particles of mesh.</p> <p>14 Q. Will you be offering -- strike that.</p> <p>15 Do you have any opinions regarding</p> <p>16 laser-cut mesh versus mechanically cut mesh as it</p> <p>17 relates to Ms. Chrysler?</p> <p>18 A. As it relates to Ms. Chrysler, I don't have</p> <p>19 any specific opinions regarding how mesh is cut.</p> <p>20 Q. Okay. Do you know whether Ms. Chrysler's</p> <p>21 mesh was laser cut? Or mechanically cut?</p> <p>22 A. I don't recall seeing which it was. I'm</p> <p>23 not -- I don't recall which one it was.</p> <p>24 Q. As it relates to your opinion in</p>	<p style="text-align: right;">Page 16</p> <p>1 off the top of my head.</p> <p>2 BY MR. SNOWDEN:</p> <p>3 Q. And I'm not trying to trick you here. I</p> <p>4 don't find the word "dyspareunia" in your report.</p> <p>5 That's why I'm asking you whether you have an</p> <p>6 opinion in this case regarding whether mesh caused</p> <p>7 any dyspareunia in Ms. Chrysler.</p> <p>8 A. Well, I don't remember her testimony. But,</p> <p>9 obviously, that's a form of vaginal pain -- or it</p> <p>10 can be. As pelvic pain, I just don't remember from</p> <p>11 her medical record whether that was occurring at the</p> <p>12 time she was having sexual intercourse.</p> <p>13 So I would have to re-review her</p> <p>14 deposition, because there were so many that I</p> <p>15 reviewed in preparation for today and tomorrow.</p> <p>16 Q. Will you be offering any opinions that the</p> <p>17 mesh implanted in Ms. Chrysler deformed while in the</p> <p>18 body?</p> <p>19 MR. CURTIS: Object to the form of the</p> <p>20 question.</p> <p>21 A. Well, based on the specimen that I had, it</p> <p>22 was a very superficial specimen that was only taken</p> <p>23 out from the urinary tract without associated</p> <p>24 supporting tissue around it. So I can extrapolate</p>
<p style="text-align: right;">Page 15</p> <p>1 Ms. Chrysler's case, does it make a difference</p> <p>2 whether the mesh is laser cut or mechanically cut?</p> <p>3 MR. CURTIS: Isn't that what you asked</p> <p>4 two questions ago?</p> <p>5 A. I -- I would have to re-review the</p> <p>6 literature regarding that, because that's not my</p> <p>7 focus as a pathologist. With respect to, I guess,</p> <p>8 the being able to distinguish an inflammatory,</p> <p>9 fibrosing reaction or foreign-body-type reaction</p> <p>10 based on that, I haven't seen pathologic --</p> <p>11 histopathologic, I guess, studies with respect to</p> <p>12 that.</p> <p>13 So I don't really know with respect to</p> <p>14 that its effect in tissue sections of humans.</p> <p>15 BY MR. SNOWDEN:</p> <p>16 Q. Will you be offering any opinion in this</p> <p>17 case that the mesh implanted in Ms. Chrysler caused</p> <p>18 her dyspareunia?</p> <p>19 MR. CURTIS: Object to the form of the</p> <p>20 question.</p> <p>21 (Document review.)</p> <p>22 A. I would have to re-review her aspects of</p> <p>23 the deposition with regards to how she describes her</p> <p>24 dyspareunia, because I don't -- I don't recall that</p>	<p style="text-align: right;">Page 17</p> <p>1 from the degree of fibrosis I can see in just that</p> <p>2 very minimal amount of tissue that I had that it's</p> <p>3 much more likely than not that the amount of mesh</p> <p>4 remaining likely shows deformation.</p> <p>5 BY MR. SNOWDEN:</p> <p>6 Q. Other than the minimal amount of tissue</p> <p>7 associated with the specimen that you received, do</p> <p>8 you have any other basis for your opinion regarding</p> <p>9 deformation?</p> <p>10 A. No. I would say that the fact that I was</p> <p>11 able to find so many pertinent features within this</p> <p>12 very minimal amount of tissue speaks to the fact of</p> <p>13 what a prominent response she more likely than not</p> <p>14 has in the remaining mesh that is still implanted.</p> <p>15 Q. Are you offering any opinion in this case</p> <p>16 regarding migration of the mesh?</p> <p>17 MR. CURTIS: Object to the form of the</p> <p>18 question.</p> <p>19 A. Yes.</p> <p>20 BY MR. SNOWDEN:</p> <p>21 Q. And what is that?</p> <p>22 A. It's that it migrated.</p> <p>23 Q. Okay. Where did it migrate from and where</p> <p>24 did it migrate to?</p>

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<p style="text-align: right;">Page 18</p> <p>1 A. Well, it migrated into the urethra, and I 2 would imagine the surgeon didn't put it in the 3 urethra. So that's the very least of where it 4 migrated. 5 Q. Other than you imagining that the surgeon 6 did not place it in the urethra, what's the basis 7 for your opinion that it migrated? 8 A. Well, let me clarify since you 9 sarcastically said "imagine." 10 I -- she -- her symptoms of pain 11 occurred years after she had the TVT placed. So if 12 my recollection is correct -- so she had that 13 performed on June of 2003, and the mesh within the 14 urethra wasn't noted until 2013. 15 So it's not that I'm imagining that it 16 wasn't placed. That doesn't seem -- that is likely 17 not an occurrence that mesh would be sitting within 18 her urethra for a decade. 19 So that's the basis of my opinion that 20 it migrated and that it wasn't placed there. 21 Q. And I didn't mean to offend. I was just 22 trying to use your words appropriately in the 23 question. 24 So as I understand it, your basis is</p>	<p style="text-align: right;">Page 20</p> <p>1 (Document review.) 2 A. Well, I do in the paragraph starting on 3 June 24th, 2003. It said "associated" -- "with 4 associated right groin pain and sharp right lower 5 quadrant pain." 6 And then I talked about, presented 7 with complaints of sharp pelvic pain for one month 8 in August 2014. 9 So I don't know where you're getting 10 that I didn't talk about pain. 11 BY MR. SNOWDEN: 12 Q. I'm sorry. We've done a lot of these. I 13 didn't mean -- 14 MR. AYLSTOCK: Now I'm confused. And 15 the names are all -- they're all the same. 16 MR. SNOWDEN: So I apologize. I 17 wasn't trying to trick you. Okay? 18 MR. CURTIS: Did you just misstate 19 your question? 20 MR. SNOWDEN: Yes. 21 MR. CURTIS: So the question is 22 withdrawn, and we're starting again. Is that right? 23 MR. SNOWDEN: Yes. 24 MR. CURTIS: Okay.</p>
<p style="text-align: right;">Page 19</p> <p>1 that the pain appeared years later. Is that -- in a 2 nutshell, is that basically it? 3 A. That's -- 4 MR. CURTIS: Object to the form of the 5 question. 6 A. My recollection is that her -- the type of 7 pain that I'm associating the histopathologic 8 features with occurred after her mesh was implanted. 9 BY MR. SNOWDEN: 10 Q. When did that begin? 11 A. I don't have -- she talks about it, I 12 think, in her deposition. And I don't have the 13 specific records. I don't document the specific 14 records of her different pain, because she had pain 15 postoperatively which was different than this type 16 of pain. 17 So I would have to go through her 18 records again to be able to say -- and look through 19 her deposition to be able to say when this different 20 quality pain started. 21 Q. Would you agree with me that your summary 22 of the pertinent medical history in your report that 23 you signed on May 4th, 2016, doesn't recount any 24 medical records that mention pain?</p>	<p style="text-align: right;">Page 21</p> <p>1 MR. SNOWDEN: I was not trying to put 2 anything over on you. 3 MR. CURTIS: Okay. The doctor's 4 stamina is putting us all to shame, so let's keep 5 moving. 6 BY MR. SNOWDEN: 7 Q. So, Doctor, in your review of the specimen, 8 did you identify any nerves? 9 A. No. I didn't identify any prominent 10 nerves. 11 Q. Did you identify any nerves? 12 A. Well, I mean, no. I did not identify any 13 nerves. If there were -- if there was an axon 14 present, I wouldn't have seen it with what I had. 15 But I didn't identify any histologically confirmed 16 nerves. 17 Q. Did you identify any nerve receptors in the 18 specimen? 19 A. I didn't use any stains to try and identify 20 any nerve specimens -- or nerve receptors. 21 Q. If you didn't see any nerves, is it fair to 22 say you didn't see any neuromas? 23 A. There were no neuromas in the superficial 24 specimen.</p>

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<p style="text-align: right;">Page 22</p> <p>1 Q. Your description of the slides on page 5</p> <p>2 list two HNE-stained slides and one</p> <p>3 immunohistochemical stain using an antibody directed</p> <p>4 at the S100 protein.</p> <p>5 Do you see that?</p> <p>6 A. Yes.</p> <p>7 Q. Is there any reason why you didn't take any</p> <p>8 pictures or include any pictures of the S100 stain?</p> <p>9 A. It didn't show anything.</p> <p>10 Q. Did you take any photographs that you</p> <p>11 didn't -- photomicrographs that you didn't include</p> <p>12 in your report?</p> <p>13 A. I don't recall. I typically include the</p> <p>14 pictures that I take.</p> <p>15 Q. Did you find any mucosal lining in your --</p> <p>16 strike that. I'll start again.</p> <p>17 Did you find any mucosa in your</p> <p>18 specimen?</p> <p>19 A. I don't believe I did. No.</p> <p>20 Q. Did you see any tissue necrosis in the</p> <p>21 specimen?</p> <p>22 A. No.</p> <p>23 Q. Did you identify any edema in the specimen?</p> <p>24 A. Not any significant edema that I recall.</p>	<p style="text-align: right;">Page 24</p> <p>1 most likely than not it did.</p> <p>2 Q. And what's the basis for that opinion?</p> <p>3 A. Again, the basis would be the fact that I'm</p> <p>4 seeing a significant amount of fibrosis and tissue</p> <p>5 reaction in a very superficial portion of the</p> <p>6 specimen, which was completely intraluminal. And</p> <p>7 based on the fact that I'm seeing that degree of an</p> <p>8 inflammatory and fibrous response in a superficial</p> <p>9 portion of a minute specimen that I have, I would</p> <p>10 extrapolate that if I were to review material from</p> <p>11 within the actual stroma of the vaginal area, that</p> <p>12 it would be significantly fibrotic, significantly</p> <p>13 inflamed, deformed, and contracted based on my</p> <p>14 review of the superficial aspect that I have in this</p> <p>15 specimen.</p> <p>16 Q. You haven't reviewed any specimen of the --</p> <p>17 her tissue other than this superficial specimen. Is</p> <p>18 that right?</p> <p>19 A. This is the only specimen that I have</p> <p>20 reviewed in this case.</p> <p>21 Q. For Ms. Chrysler, are there any clinical</p> <p>22 symptoms you're correlating with the contraction</p> <p>23 that occurred, in your opinion?</p> <p>24 A. Her pain, more likely than not.</p>
<p style="text-align: right;">Page 23</p> <p>1 Q. Did you identify any signs of infection in</p> <p>2 the specimen?</p> <p>3 A. Well, there was areas of both acute and</p> <p>4 chronic inflammation, which can be indicative of an</p> <p>5 infection.</p> <p>6 Q. Was the quantity of acute inflammation that</p> <p>7 you saw in this specimen sufficient for you to say,</p> <p>8 to a reasonable degree of medical certainty, that</p> <p>9 there was an infection here?</p> <p>10 A. Well, to say that there's an infection with</p> <p>11 a -- well, I should say: To say that there's an</p> <p>12 infection, I would need to identify an infectious</p> <p>13 agent.</p> <p>14 And I didn't have any material to do</p> <p>15 any sort of supplemental histochemical stains to</p> <p>16 identify there was an infection -- infectious agent</p> <p>17 present or not, so I can't say whether there was an</p> <p>18 infection. But I didn't see any evidence of one.</p> <p>19 Q. Do you have an opinion in this case</p> <p>20 regarding whether Ms. Chrysler's mesh contracted?</p> <p>21 A. Was it contracted? Was that your last --</p> <p>22 Q. Yes. Sorry. Contracted.</p> <p>23 A. Well, along the lines of what I said</p> <p>24 earlier about the deformation, I would say that yes,</p>	<p style="text-align: right;">Page 25</p> <p>1 Q. Anything else?</p> <p>2 A. Well, besides, obviously, the fact that it</p> <p>3 was eroded into the urethra.</p> <p>4 Q. Anything else?</p> <p>5 A. Not that I can think of.</p> <p>6 Q. Were you able to identify any pore spaces</p> <p>7 in the specimen that you reviewed?</p> <p>8 A. It was fragmented -- too fragmented.</p> <p>9 Q. Okay. So you were not able to do so?</p> <p>10 A. No.</p> <p>11 Q. Do you have an opinion in this case when</p> <p>12 the -- well, let me start over. I just want to make</p> <p>13 sure that I've got this.</p> <p>14 Is it your opinion that the fibrosis</p> <p>15 around the mesh led to the contraction? Is that the</p> <p>16 right --</p> <p>17 A. That's one aspect of the contraction.</p> <p>18 Q. Okay. What are the other aspects of the</p> <p>19 contraction?</p> <p>20 A. Fibrosis that would be encapsulating</p> <p>21 that -- based on my review of these slides, I would</p> <p>22 imagine I would -- it's my opinion it would likely</p> <p>23 be present, given the fact that I'm seeing so much</p> <p>24 fibrosis in this superficial aspect that would be</p>

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<p style="text-align: right;">Page 26</p> <p>1 surrounding it.</p> <p>2 Q. When -- do you have an opinion in this case</p> <p>3 of when that fibrosing reaction would have begun in</p> <p>4 Ms. Chrysler?</p> <p>5 A. Well, in general, fibrosis begins in any</p> <p>6 patient after a surgical procedure in the range of a</p> <p>7 few weeks. And it would have obviously changed in</p> <p>8 quality over time and degree, depending on how it</p> <p>9 migrated, where it migrated to.</p> <p>10 So I would imagine, as in most</p> <p>11 patients, it would have begun shortly after the time</p> <p>12 that it was implanted.</p> <p>13 Q. Do you have an opinion when the fibrosis</p> <p>14 was sufficient enough to contract mesh in any</p> <p>15 clinically significant way?</p> <p>16 A. In this particular case?</p> <p>17 Q. Yes. In this case.</p> <p>18 A. Well, beginning within a month. When you</p> <p>19 have fibrosis in general, it would cause changes in</p> <p>20 the mesh.</p> <p>21 Q. If you turn to page 4 of your report under</p> <p>22 the heading "Marion Chrysler," you have listed there</p> <p>23 in the past medical history diverticulosis.</p> <p>24 Do you see that?</p>	<p style="text-align: right;">Page 28</p> <p>1 A. In the postoperative period, yes, that</p> <p>2 would lead to inflammation.</p> <p>3 Q. Does it also lead to fibrosis?</p> <p>4 A. It would lead to some fibrosis in the area</p> <p>5 of the surgery. Correct.</p> <p>6 Q. Does it carry with it a risk of adhesions?</p> <p>7 A. Yes. You can have adhesions following a</p> <p>8 total abdominal hysterectomy and right</p> <p>9 salpingo-oophorectomy.</p> <p>10 Q. Do you -- strike that.</p> <p>11 Do you place any significance on the</p> <p>12 pathological examination and the findings which you</p> <p>13 list in your summary from the hysterectomy?</p> <p>14 A. Could you repeat that?</p> <p>15 Q. Yeah. So I'm looking at the sentence that</p> <p>16 begins, "Pathologic examination of this</p> <p>17 specimen ..." which I believe refers to the</p> <p>18 abdominal hysterectomy.</p> <p>19 A. Um-hmm.</p> <p>20 Q. Is there any significance to your opinion</p> <p>21 in this case from your review of the records</p> <p>22 regarding that pathologic examination?</p> <p>23 (Document review.)</p> <p>24 A. No.</p>
<p style="text-align: right;">Page 27</p> <p>1 A. Yes.</p> <p>2 Q. Did you consider that in your opinion in</p> <p>3 this case?</p> <p>4 A. Yes.</p> <p>5 Q. What role did that play in your opinion?</p> <p>6 A. I don't think it's related to anything.</p> <p>7 Q. Okay. Why not?</p> <p>8 A. Because that's my medical opinion. It's</p> <p>9 diverticulosis. Diverticulosis -- a large</p> <p>10 percentage of the population over a certain age has</p> <p>11 diverticulosis, and it causes absolutely zero</p> <p>12 problems unless it becomes diverticulitis and is</p> <p>13 inflamed and infected.</p> <p>14 And there's no evidence that she ever</p> <p>15 had diverticulitis that I could see, and</p> <p>16 diverticulosis by itself is painless.</p> <p>17 Q. In the next line you have that she</p> <p>18 underwent a total abdominal hysterectomy and right</p> <p>19 salpingo-oophorectomy?</p> <p>20 A. Yes.</p> <p>21 Q. Is that a significant surgery?</p> <p>22 A. Yes.</p> <p>23 Q. Does that in the postoperative period lead</p> <p>24 to inflammation?</p>	<p style="text-align: right;">Page 29</p> <p>1 BY MR. SNOWDEN:</p> <p>2 Q. Let's turn to Figure 1 of your report on</p> <p>3 page 7. What are we looking at here?</p> <p>4 A. So we're looking at a fragment of the</p> <p>5 fibrous tissue that has some acute inflammatory</p> <p>6 cells embedded within it.</p> <p>7 Q. Where on this photo are the acute</p> <p>8 inflammatory cells?</p> <p>9 A. Really all along the fibrous tissue in</p> <p>10 clusters.</p> <p>11 Q. Where was the mesh in relation to this</p> <p>12 fragment?</p> <p>13 A. It would be adjacent to it.</p> <p>14 Q. On which side?</p> <p>15 A. Likely this side.</p> <p>16 Q. The left side?</p> <p>17 A. Correct.</p> <p>18 Q. What's your basis for that opinion?</p> <p>19 A. The contour of the tissue and the outer</p> <p>20 element, the right side, how it has a different</p> <p>21 quality to the tissue.</p> <p>22 Q. Are you able to -- strike that.</p> <p>23 What's the significance of those</p> <p>24 findings to your opinion in this case?</p>

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<p style="text-align: right;">Page 30</p> <p>1 A. Well, the presence of acute inflammation in 2 the setting of fibrosis or otherwise often leads to 3 symptomatology of pain. 4 Q. Anything else significant about this photo? 5 A. Not other than the presence of the 6 fibrosis. 7 Q. And if you turn to Figure 5, is Figure 5 -- 8 at least the middle portion of Figure 5 -- the same 9 piece of tissue that's shown in Figure 1? 10 A. Yes. 11 Q. So looking at Figure 5, you've already told 12 me about that piece in the middle. Is there any 13 significance -- 14 Well, first, what else are we looking 15 at in those other fragments here? 16 MR. CURTIS: Object to the form of the 17 question. 18 A. We're just looking at other fragments of 19 fibrous tissue. 20 BY MR. SNOWDEN: 21 Q. And what's the significance of that finding 22 to your opinion in this case? 23 A. It just highlights the fibrosis. 24 Q. Are you able to tell me how large these</p>	<p style="text-align: right;">Page 32</p> <p>1 tissue that would be adjacent to a mesh filament 2 with admixed both acute and chronic inflammatory 3 cells. 4 Q. And where in Figure 2 are the acute 5 inflammatory cells? 6 A. They're within the fibrous tissue in the 7 middle of the picture. 8 Q. Are you able, looking at this Figure 2, to 9 identify any single acute inflammatory cells? 10 A. Yes. 11 Q. Could you circle them for me. 12 (Witness complies.) 13 A. Those would be the ones that I can identify 14 at this magnification. 15 BY MR. SNOWDEN: 16 Q. Is there anything else significant about 17 Figure 2? 18 A. No. 19 Q. Figure 3, if you'd turn there, please. 20 What is shown in this photomicrograph? 21 A. It shows fibrous tissue with chronic 22 inflammation, some foreign body giant cells. That's 23 about it. 24 Q. In your figure legend, you have written,</p>
<p style="text-align: right;">Page 31</p> <p>1 fragments are in Figure 5? 2 A. No. 3 Q. Other than the mesh you told us that's to 4 the left of the center portion of Figure 5, can you 5 identify any other areas on Figure 5 where there 6 would have been mesh? 7 A. Well, in the upper right-hand portion, it's 8 hard to tell with that fragment based on the 9 orientation of the tissue. So I can't really 10 comment. But I -- as far as which side it would be 11 on, if it would be on one of those sides. 12 But I can say that that tissue is 13 consistent with tissue adjacent to a mesh because it 14 has the same qualities that the others do that 15 clearly have mesh adjacent to them. 16 Q. And for that fragment on the right-hand 17 side of Figure 5, how are you able to determine 18 that's connective tissue versus a collection of 19 protein? 20 A. Based on its appearance. 21 Q. Let's go back to Figure 2 -- well, go to 22 Figure 2, please. 23 What are you showing with this figure? 24 A. I am showing another fragment of fibrous</p>	<p style="text-align: right;">Page 33</p> <p>1 "Mesh pore space showing a brisk chronic 2 inflammatory infiltrate." And you -- then you 3 continue. 4 Do you see that? 5 A. Um-hmm. 6 Q. What do you mean by "brisk chronic 7 inflammatory infiltrate"? 8 A. Well, the entire tissue in this area is 9 involved by inflammatory cells. It's just a 10 descriptive term. 11 Q. And I'm just -- I'm trying to understand 12 what you're trying to describe when you say that 13 it's brisk. Is it the entire tissue is involved? 14 A. It just means there's several -- it's just 15 a -- it's just a descriptive term. 16 Q. Can you tell us what the clinical 17 significance of what we see in Figure 3 is? 18 A. Well, the clinical significance would be 19 that we're seeing evidence of a foreign body 20 granulomatous response to mesh that is outside of 21 the normal confines of the patient's tissues since 22 this was removed within the urethra. 23 So that, by definition, is pathologic 24 and would lead to the symptoms that she described.</p>

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1 Q. Which symptoms in particular? Is it all of  
2 them? Is it some of them?

3 A. The pain.

4 Q. Other than the macrophages, lymphocytes,  
5 and scattered foreign body multinucleated giant  
6 cells, is there any other type of tissue present  
7 here in Figure 3?

8 A. Well, it's within fibrous tissue. And it  
9 looks like there's some like proteinaceous fibrin or  
10 blood products along the edge. But I don't see any  
11 evidence of skeletal muscle; I don't see any  
12 evidence of smooth muscle; I don't see any  
13 epithelium.

14 Q. Do you have an opinion where the mesh was  
15 in Figure 3?

16 A. It's hard to say from this picture alone  
17 where it would be.

18 Q. Did you use the polarized lens -- I'm  
19 sorry -- polarized filters when you looked at this  
20 specimen?

21 A. Yes.

22 Q. Do you recall whether there was mesh in the  
23 specimen?

24 A. I don't recall seeing any mesh with

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1 polarization microscopy.

2 Q. Okay. Did you see any with light  
3 microscopy?

4 A. Well, that is light microscopy.

5 Q. Nonpolar, regular light?

6 A. Not that I recall.

7 Q. In Figure 4, what are we looking at here?

8 A. It's a low magnification view of basically  
9 the same thing.

10 Q. So what type of tissue are we looking at  
11 here?

12 A. We're looking at a lot of fragments of  
13 fibrous tissue, some serum fibrin. That would be  
14 the brighter pink.

15 Q. Anything else present in the specimen --  
16 strike that.

17 Anything else present in this figure?

18 A. Not that I can appreciate at this  
19 magnification.

20 Q. Do you attribute any -- any of  
21 Ms. Chrysler's complications to what you see in  
22 Figure 4?

23 A. Well, Figure 4 shows a lot of tissue. So  
24 at higher magnification, yes, but I can't point out

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1 the particular inflammatory cells from this  
2 magnification. This is intended just to give an  
3 overall view of the specimen.

4 Q. From your review -- and I think we've gone  
5 through all five figures now.

6 From your review of Ms. Chrysler's  
7 specimen, did you find that the tissue had been  
8 properly preserved?

9 A. Well, it looked -- the histology was not  
10 great, so I don't know about how it was -- if it sat  
11 out not in formalin when it was received or if when  
12 they removed it, if they did something. It was  
13 interpretable, but it was not ideal.

14 Q. Did the quality of the specimen impact your  
15 analysis in any way?

16 A. No. I would say, if anything, had it been,  
17 you know, better preserved, I would have been able  
18 to make more specific findings.

19 But I was actually surprised, given  
20 the quality of the tissue, that I was able to see as  
21 much cellular detail as I did, being able to  
22 identify the acute and chronic inflammatory cells  
23 and the multinucleated giant cells, which given the  
24 small amount of tissue, I was, you know, surprised

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1 that I could make those out with light microscopy.

2 Q. Does any of the -- and we're talking about  
3 Ms. Chrysler in particular. But if the tissue sat  
4 out for a couple of years without being in formalin,  
5 does that affect the volume of the tissue at all?

6 MR. CURTIS: Object to the form of the  
7 question.

8 A. Yes. It would dry up and -- it would dry  
9 up. It would kind of -- it would look like it would  
10 shrink.

11 BY MR. SNOWDEN:

12 Q. So what we're looking at here in  
13 Ms. Chrysler's specimen, in addition to whatever  
14 affects tissue-processing themselves have on tissue,  
15 we also have an added layer of -- hold on a second.  
16 Strike that.

17 (Exhibit 2 marked.)

18 BY MR. SNOWDEN:

19 Q. I'm handing you what's been marked as  
20 Exhibit 2.

21 Doctor, do you recall reviewing this  
22 record in your review of the records in this case?

23 A. It looks familiar.

24 Q. Okay. And if we look at the collection

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<p style="text-align: right;">Page 38</p> <p>1 date, April 2013, does that correlate with the date 2 of the surgery from which you received a specimen? 3 A. Yes. 4 Q. And it appears from this record that there 5 was a gross only done. Is that correct? 6 A. Yes. 7 Q. And if we look at the gross description, it 8 mentions that it was received in the fresh state -- 9 "Received in the fresh state is a blood-tinged 10 synthetic mesh-like gray-white foreign object 11 measuring 0.8 by 0.4 by 0.1 cm." 12 Do you see that? 13 A. Yes. 14 Q. Well, is it standard practice if it comes 15 fresh and you're not going to put it through that 16 you just -- strike that. 17 Do you know whether they put formalin 18 on it after this point? 19 MR. CURTIS: Object to the form of the 20 question. 21 A. I don't know. They don't specifically say 22 whether they put formalin or not. 23 BY MR. SNOWDEN: 24 Q. From your review of the specimen, does it</p>	<p style="text-align: right;">Page 40</p> <p>1 when you use the word "aspect"? 2 MR. SNOWDEN: And it's -- okay. 3 BY MR. SNOWDEN: 4 Q. Do you have an opinion as to what portion 5 of the design of the TVT led to the complications in 6 Ms. Chrysler's case? 7 MR. CURTIS: I'll object to the form 8 of the question. 9 THE WITNESS: Could you repeat that? 10 (The record was read as requested: 11 "Do you have an opinion as to what 12 portion of the design of the TVT led 13 to the complications in Ms. Chrysler's 14 case?") 15 MR. CURTIS: I renew the objection for 16 the reasons stated. 17 A. Well, I guess, as I've stated before, with 18 respect to small pore size and the overall heavy 19 weight of the polypropylene mesh, that those were 20 contributing factors to the inflammatory and fibrous 21 reaction that we see in Ms. Chrysler's specimen. 22 BY MR. SNOWDEN: 23 Q. Anything else? 24 A. I would say that would be the main thing in</p>
<p style="text-align: right;">Page 39</p> <p>1 appear that the tissue sat out for some time? 2 A. You can see this processing artifact from a 3 number of different causes, so I couldn't say. 4 Q. Okay. What aspect of the TVT device led to 5 the fibrosing reaction that you described in these 6 figures? 7 A. I don't know what you mean. 8 Q. Yeah. Do you have an opinion as to a 9 certain aspect of the TVT device that led to the 10 fibrosis that we see in these figures? 11 A. I guess I don't understand what you mean by 12 "aspect" of it. 13 Q. Is there something about the TVT mesh that, 14 in your opinion, caused -- causes and caused, in 15 Ms. Chrysler's case, the fibrosis you see here? 16 A. Again, I don't understand what aspect, 17 other than the polypropylene material. But I don't 18 know what -- if you're talking about something else, 19 I don't -- I guess I don't understand the question. 20 MR. CURTIS: Yeah. I object because I 21 think it's getting back into the general area. 22 Are you talking about the thickness of 23 the filaments or the size of the pores or the weight 24 of the mesh, or just -- what are you talking about</p>	<p style="text-align: right;">Page 41</p> <p>1 this case. 2 Q. Do you have any -- will you be offering any 3 opinions in this case regarding how Ms. Chrysler has 4 done following the excision of the mesh specimen 5 that you reviewed? 6 MR. CURTIS: Object to the form of the 7 question. 8 A. As I stated earlier, I will answer 9 questions that are asked of me at trial if it's 10 relative to what I have reviewed. And I have the 11 opinion that I can relate my review of her specimens 12 to her current condition. 13 BY MR. SNOWDEN: 14 Q. And the -- so I understand it, do you have 15 any basis for your opinion -- strike that. 16 What's the basis for that opinion? 17 A. What's the basis for my -- I don't 18 understand. What's basis for my opinion that I'll 19 have an opinion? It's that I'll have an opinion if 20 I'm asked a question. 21 So as I've said multiple times today, 22 if someone asks me a question and I'm comfortable as 23 a physician and pathologist who's reviewed the 24 material answering the question, I'll answer the</p>

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<p style="text-align: right;">Page 42</p> <p>1 question, just as you've asked me a number of  2 questions that may not necessarily be completely  3 related to what I have reviewed. But if I'm  4 comfortable answering the question, I'll answer the  5 question.  6 I'm going to answer questions that I'm  7 asked. Whether I'm -- the person asking the  8 question is allowed to ask me that question, I don't  9 know. I don't get involved in that.  10 Q. Do you have an opinion regarding any  11 symptomatology of Ms. Chrysler's following the mesh  12 revision surgery in which you received the specimen?  13 MR. CURTIS: Rebecca, I'm sorry. May  14 I hear that again?  15 (The record was read as requested:  16 "Do you have an opinion regarding any  17 symptomatology of Ms. Chrysler's  18 following the mesh revision surgery in  19 which you received the specimen?")  20 A. Yes. I would say that more likely than  21 not, her complaints of sharp pelvic pain are related  22 to the findings that I'm seeing microscopically, and  23 correlate with the likely response in her tissue to  24 the mesh that is still present within that region.</p>	<p style="text-align: right;">Page 44</p> <p>1 Q. Did you consider that -- at least in one of  2 Dr. Iakovlev's publications, he reports pain with  3 retropubic slings of less than 2.5 percent?  4 A. I would have to see the publication.  5 Q. Do you know whether you've reviewed that  6 one?  7 A. I've reviewed a lot of publications. I  8 would have to review what you're talking about  9 before I could really, I guess, accurately answer  10 questions about them.  11 Q. Had Dr. Iakovlev authored a publication  12 showing a rate of pain at less than 2.5 percent  13 in -- with the -- after the implantation of  14 retropubic mid-urethral slings, what impact would  15 that have on your opinion?  16 MR. CURTIS: Object to the form of the  17 question.  18 He just told you that he needs to look  19 at the material.  20 A. Again, I would have to look at the context  21 of that study and that data to give you any sort of  22 informative answer about the numbers that you're  23 quoting.  24</p>
<p style="text-align: right;">Page 43</p> <p>1 BY MR. SNOWDEN:  2 Q. Is the basis of your opinion an  3 extrapolation of the review of the specimen and then  4 the review of her subsequent medical records?  5 A. Yes. That would be the main aspect.  6 Q. In your opinion -- well, strike that.  7 When the TVT eroded into Ms. Chrysler's  8 urethra, what caused the pain?  9 A. I would say that the fact that there was a  10 foreign body eroding through a bodily surface caused  11 the pain.  12 Q. And once that mesh was removed from the  13 urethra, and you've reviewed that specimen, what  14 then causes her pain?  15 A. Well, there is still likely mesh around  16 that area, in which it's likely scarred, inflamed,  17 entrapping nerves. All the things that are well  18 described in association with these synthetic  19 devices.  20 So based on this superficial review of  21 what's here, I would say there's no reason for me to  22 have any other opinion that those fibroinflammatory  23 reactions aren't going on in deeper aspects of the  24 mesh that are still within her tissue.</p>	<p style="text-align: right;">Page 45</p> <p>1 BY MR. SNOWDEN:  2 Q. So if Dr. Iakovlev did a literature  3 review -- a literature review that showed that  4 number, sitting here today, you're not comfortable  5 of giving an answer?  6 MR. CURTIS: I object to the question.  7 It's asked three times in a row, and it's now  8 argumentative.  9 A. Again, I will answer, perhaps slower and  10 more clearly, that I would have to review any  11 article that you're quoting in order to feel  12 comfortable addressing any sort of number that  13 you're discussing, because just hearing you say that  14 there is a less than 2.5 percent incidence of pain,  15 I would have to see if that took into account  16 patients that had mesh slicing through their  17 urethra, because I can't imagine having that kind of  18 a physical finding and not having evidence of pain.  19 So I have no way of responding to that  20 article without reviewing it.  21 BY MR. SNOWDEN:  22 Q. Are you familiar with the Schimpf  23 meta-analysis?  24 A. I'm not. I don't recall.</p>

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<p style="text-align: right;">Page 46</p> <p>1 Q. In rendering your -- in coming to your 2 opinion that Ms. Chrysler's post-excision pain was 3 caused by the TVT, did you consider any literature 4 on the rates of pain with TVT? 5 A. I don't understand that question. 6 MR. SNOWDEN: Do you want to read it 7 back slowly for him? 8 MR. CURTIS: Okay. Let's get an 9 answer, then we'll take a break; and we'll all move 10 slowly after that. 11 (The record was read as requested: 12 "In coming to your opinion that Ms. 13 Chrysler's post-excision pain was 14 caused by the TVT, did you consider 15 any literature on the rates of pain 16 with TVT?") 17 A. I would say that if someone's having pain 18 after TVT, it doesn't matter what the rates 19 published of pain with TVT is, because someone is 20 having pain with TVT. 21 So am I aware of studies talking about 22 the incidence of pain post TVT? Yes. And that's 23 important information to take into account for 24 patients deciding whether they're going to have a</p>	<p style="text-align: right;">Page 48</p> <p>1 Q. As you sit here today, do you have an 2 opinion that Ms. Chrysler's TVT mesh degraded 3 in vivo? 4 MR. CURTIS: Objection. 5 A. As I sit here today, I have not 6 specifically seen evidence of degradation in any of 7 her mesh that I have reviewed. 8 BY MR. SNOWDEN: 9 Q. How did Ms. Chrysler's pain -- well, strike 10 that. 11 (Pause in proceedings.) 12 BY MR. SNOWDEN: 13 Q. If we look at your section, 14 "Marion Chrysler," paragraph beginning on 15 6/24/2003 -- are you there? 16 A. Yes. 17 Q. 6/24/2003, that's the date of the TVT mesh 18 implantation. Is that right? 19 A. Yes. 20 Q. The next line you have, "Her postoperative 21 course was significant for urinary retention with 22 difficulty voiding ..." 23 Do you see that? 24 A. Yes.</p>
<p style="text-align: right;">Page 47</p> <p>1 TVT procedure or not. 2 But the fact of the matter is, she is 3 one of those patients that had pain with TVT, and 4 it's not a hypothetical situation. She had mesh in 5 her urethra. That doesn't really get much clearer 6 than that. So, yes, I take that information into 7 account, but I don't think that it really applies in 8 this case. 9 MR. SNOWDEN: Did you still want to 10 take a break? 11 MR. CURTIS: Yeah. Let's take a 12 break. 13 (Recess from 5:30 p.m. to 5:35 p.m.) 14 BY MR. SNOWDEN: 15 Q. Did you find any degradation bark in 16 Ms. Chrysler's specimen? 17 A. No. 18 Q. Are you offering any opinions in this case 19 that Ms. Chrysler's TVT mesh degraded in vivo? 20 A. I haven't reviewed it. I haven't reviewed 21 any evidence of that in the tissue that I have. 22 If I have other tissue from other 23 sources that's made available to me, then I would be 24 able to evaluate for that.</p>	<p style="text-align: right;">Page 49</p> <p>1 Q. Sorry. I didn't read the whole thing. 2 "... that lasted several months." 3 Do you see that? 4 A. Yes. 5 Q. What significance, if any, did the fact 6 that her postoperative course was significant for 7 urinary retention with difficulty voiding have on 8 your opinions in this case? 9 A. I would say that's not really in my purview 10 as a pathology expert to comment on her clinical 11 differential for urinary retention. 12 Q. Why not? 13 A. Because I didn't examine her. So I have 14 no -- there are several different clinical 15 indications -- or clinical etiologies, I should 16 say -- for urinary retention and difficulty voiding 17 postoperatively that I wouldn't be able to comment 18 on. I would leave that to a clinician who was 19 examining her. 20 Q. Would you agree that one of those 21 etiologies is a sling placed with tension against 22 the urethra? 23 MR. CURTIS: Object to the form of the 24 question.</p>

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<p style="text-align: right;">Page 50</p> <p>1 He said this is not his field.</p> <p>2 A. As I said already, that's not -- that's not</p> <p>3 my job to do a clinical differential diagnosis for</p> <p>4 her symptoms without having any tissue to go by.</p> <p>5 BY MR. SNOWDEN:</p> <p>6 Q. And I can respect that.</p> <p>7 But, Doctor, do you have -- I think you</p> <p>8 told us earlier you have a migration opinion in this</p> <p>9 case. Is that true?</p> <p>10 A. Yes.</p> <p>11 Q. Your opinion is that the mesh migrated in</p> <p>12 Ms. Chrysler.</p> <p>13 A. Into the urethra. Yes.</p> <p>14 Q. So what I want to know is -- and feel free</p> <p>15 if you need to defer to urogynae colleagues -- where</p> <p>16 did it migrate from?</p> <p>17 A. From outside of the urethra to within it.</p> <p>18 Q. How do you know that if you're going to</p> <p>19 defer to urogynecology colleagues on whether the</p> <p>20 mesh was placed too tight or where the mesh was</p> <p>21 placed?</p> <p>22 MR. CURTIS: Object to the form of the</p> <p>23 question. It's argumentative.</p> <p>24 A. Well, as I said earlier when we discussed</p>	<p style="text-align: right;">Page 52</p> <p>1 A. I considered it and thought that it didn't</p> <p>2 have anything to do with the fact that there was</p> <p>3 mesh inside her urethra. Because I would imagine</p> <p>4 that if there was -- it's my opinion that if there</p> <p>5 was mesh inside her urethra, that that would have</p> <p>6 made it difficult for her to self-catheterize.</p> <p>7 Q. How about if the mesh was placed tightly</p> <p>8 under the urethra?</p> <p>9 MR. CURTIS: Object to the form of the</p> <p>10 question.</p> <p>11 A. I don't know about "placed tightly under</p> <p>12 the urethra."</p> <p>13 Again, I didn't exam her -- I</p> <p>14 didn't -- at the time, I didn't do any</p> <p>15 urogynecologic studies. But what I'm, again,</p> <p>16 discussing with regards to the mesh migration in</p> <p>17 this case is that she was able to self-catheterize</p> <p>18 postoperatively. So if there was mesh placed within</p> <p>19 her urethra, I wouldn't think that she would be able</p> <p>20 to do that.</p> <p>21 And so, by definition, in my opinion,</p> <p>22 it migrated to its position where it was when it was</p> <p>23 excised in 2013.</p> <p>24</p>
<p style="text-align: right;">Page 51</p> <p>1 the migration, there's nothing to indicate to me</p> <p>2 that her mesh was initially placed within her</p> <p>3 urethra.</p> <p>4 So if I have mesh that I'm examining</p> <p>5 that's within her urethra, and by definition my</p> <p>6 conclusion is that it was not initially placed</p> <p>7 within her urethra, then without seeing other</p> <p>8 evidence of pathology, my conclusion is that, more</p> <p>9 likely than not, it migrated into her urethra.</p> <p>10 BY MR. SNOWDEN:</p> <p>11 Q. And what's the basis for your opinion that</p> <p>12 it wasn't placed there?</p> <p>13 A. Because her pain that she described later</p> <p>14 on in 2012 and further beyond 2012 was reported to</p> <p>15 be different than the pain she had before and</p> <p>16 different than her urinary symptoms.</p> <p>17 Q. If two days -- well, do you have an opinion</p> <p>18 regarding what role -- well, strike that. Let me</p> <p>19 start over.</p> <p>20 Did you consider in your opinion in</p> <p>21 this case the fact that Ms. Chrysler needed a</p> <p>22 catheter to void two days postoperatively?</p> <p>23 A. Yes, I did consider that.</p> <p>24 Q. And how did you consider it?</p>	<p style="text-align: right;">Page 53</p> <p>1 BY MR. SNOWDEN:</p> <p>2 Q. Do you have an opinion whether mesh placed</p> <p>3 with such tension under the urethra that the patient</p> <p>4 has voiding difficulties for several months could</p> <p>5 later lead to erosion into the urethra?</p> <p>6 MR. CURTIS: Object to the form of the</p> <p>7 question.</p> <p>8 A. Again, I don't know the surgical</p> <p>9 complications in that literature with respect to how</p> <p>10 they're placed -- how the different surgeons place</p> <p>11 them under tension versus not tension. If it was</p> <p>12 felt that it was placed with tension at the time, I</p> <p>13 don't have an opinion regarding that.</p> <p>14 BY MR. SNOWDEN:</p> <p>15 Q. Are you offering any opinion -- well,</p> <p>16 strike that.</p> <p>17 Do you have any opinion in this case</p> <p>18 regarding placement?</p> <p>19 MR. CURTIS: Do you mean placement of</p> <p>20 the mid-urethral sling?</p> <p>21 MR. SNOWDEN: Yes. Whether it was</p> <p>22 proper or improper. I'll clean it up.</p> <p>23 BY MR. SNOWDEN:</p> <p>24 Q. Do you have an opinion in this case</p>

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<p style="text-align: right;">Page 54</p> <p>1 regarding whether the TVT sling implanted in 2 Ms. Chrysler was implanted properly or improperly? 3 MR. CURTIS: Object to the form of the 4 question. This is not his field, as I understand 5 it. 6 A. Again, as I've already said with regards to 7 how the TVT was placed, I can't comment on how it 8 was placed and with what surgical technique that 9 particular surgeon did as I didn't exam her. 10 But what I can say is that, based on 11 my review of her medical records, more likely than 12 not, this was not initially placed within her 13 urethra, which is where it was when it was removed. 14 So, again, by definition, it migrated. 15 BY MR. SNOWDEN: 16 Q. Putting aside your opinion of whether it 17 was placed in the urethra, are you offering an 18 opinion on the tension it was placed under the 19 mid-urethra? 20 MR. CURTIS: Object to the form of the 21 question for the reasons stated to the last several 22 questions. 23 A. I do not have any significant expertise in 24 surgical techniques of TVT placement.</p>	<p style="text-align: right;">Page 56</p> <p>1 A. I have not been consulted by any of her 2 treating physicians regarding her care. 3 Q. Outside of counsel for Ms. Chrysler, have 4 you spoken with anyone regarding Ms. Chrysler's 5 case? 6 A. I don't believe so, no. 7 Q. You did not see the mesh in vivo. Is that 8 correct? 9 A. No. I didn't see the mesh inside of 10 Ms. Chrysler. 11 Q. And during any surgery, you didn't -- you 12 weren't there to see it. 13 A. That's correct. 14 MR. SNOWDEN: Let's go off the record. 15 Give me just one minute. 16 (Pause in proceedings.) 17 BY MR. SNOWDEN: 18 Q. Doctor, how long -- strike that. 19 How many hours have you spent working 20 on this case? 21 A. Maybe around 20. 22 MR. SNOWDEN: All right. I have 23 nothing further. Thank you. 24 (Proceedings concluded at 5:50 p.m.)</p>
<p style="text-align: right;">Page 55</p> <p>1 BY MR. SNOWDEN: 2 Q. In reviewing Ms. Chrysler's specimen in 3 this case, was your review limited to light and 4 polarized light microscopy? 5 A. Yes. 6 Q. So you didn't to any scanning electron 7 microscopy. 8 A. That's correct. 9 Q. You didn't do any transmission electron 10 microscopy? 11 A. That's correct. 12 Q. You didn't do any mechanical testing -- 13 sorry. Strike that. 14 You didn't do any mechanical testing on 15 the specimen. 16 A. I did not do any mechanical testing on her 17 specimen. 18 Q. You were not in the operating room for any 19 of the procedures. Is that correct? 20 A. That's correct. I was not in the operating 21 room for any of her procedures. 22 Q. Have you been consulted by any of 23 Ms. Chrysler's treating physicians regarding 24 Ms. Chrysler?</p>	<p style="text-align: right;">Page 57</p> <p>1 - - - - - 2 E R R A T A 3 - - - - - 4 PAGE LINE CHANGE 5 _____ 6 REASON: _____ 7 _____ 8 REASON: _____ 9 _____ 10 REASON: _____ 11 _____ 12 REASON: _____ 13 _____ 14 REASON: _____ 15 _____ 16 REASON: _____ 17 _____ 18 REASON: _____ 19 _____ 20 REASON: _____ 21 _____ 22 REASON: _____ 23 _____ 24 REASON: _____</p>

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## ACKNOWLEDGMENT OF DEPONENT

I, \_\_\_\_\_, do  
 hereby certify that I have read the  
 foregoing pages, and that the same is  
 a correct transcription of the answers  
 given by me to the questions therein  
 propounded, except for the corrections or  
 changes in form or substance, if any,  
 noted in the attached Errata Sheet.

\_\_\_\_\_  
 PAUL J. MICHAELS, M.D. DATE

Subscribed and sworn  
 to before me this

\_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

My commission expires: \_\_\_\_\_

\_\_\_\_\_  
 Notary Public

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I, Rebecca J. Callow, Registered Merit  
 Reporter and Notary Public in and for the State of  
 Texas, hereby certify to the following:

That the witness, PAUL J. MICHAELS, M.D., was  
 duly sworn by the officer and that the transcript of the  
 oral deposition is a true record of the testimony given  
 by the witness;

That the original deposition was delivered to

\_\_\_\_\_  
 That pursuant to information given to the  
 deposition officer at the time said testimony was  
 taken, the following the amount of time used by  
 each party at the time of the deposition:

M. Andrew Snowden (1h20m)

Attorney for Johnson & Johnson and  
 Ethicon, Inc.

Danny L. Curtis (0h0m)

Attorney for Plaintiffs

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IN THE UNITED STATES DISTRICT COURT  
 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
 CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC ) Master File No.  
 REPAIR SYSTEM PRODUCTS )  
 PRODUCTS LIABILITY LITIGATION ) 2:12-MD-02327  
 )  
 THIS DOCUMENT RELATES TO THE ) MDL 2327  
 FOLLOWING CASES IN WAVE 2 )  
 OF MDL 200: )  
 ) JOSEPH R. GOODWIN  
 Tamara Carter, et al. v. )  
 Ethicon, Inc., et al. ) U.S. DISTRICT JUDGE  
 Civil Action No. 2:12-cv-01661 )  
 )  
 Sandra Childress, et al. v. )  
 Ethicon, Inc., et al. )  
 Civil Action No. 2:12-cv-01564 )  
 )  
 Marion Chrysler v. )  
 Ethicon, Inc., et al. )  
 Civil Action No. 2:12-cv-02060 )  
 )  
 Melissa Sanders, et al. v. )  
 Ethicon, Inc., et al. )  
 Civil Action No. 2:12-cv-01562 )  
 )  
 Ana Sierra, et al. v. )  
 Ethicon, Inc., et al. )  
 Civil Action No. 2:12-cv-01819 )  
 )  
 Toni Hernandez v. )  
 Ethicon, Inc., et al. )  
 Civil Action No. 2:12-cv-02073 )  
 )

REPORTER'S CERTIFICATE  
 ORAL DEPOSITION OF PAUL J. MICHAELS, M.D.  
 June 18, 2016

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I further certify that pursuant to FRCP Rule  
 30(f)(1) that the signature of the deponent:

[ ] was requested by the deponent or a party  
 before the completion of the deposition and is to be  
 returned within 30 days from date of receipt of the  
 transcript. If returned, the attached Changes and  
 Signature Page contains any changes and the reasons  
 therefor;

[ ] was not requested by the deponent or a  
 party before the completion of the deposition.

I further certify that I am neither counsel  
 for, related to, nor employed by any of the parties or  
 attorneys to the action in which this proceeding was  
 taken. Further, I am not a relative or employee of any  
 attorney of record in this cause, nor am I financially  
 or otherwise interested in the outcome of the action.

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SUBSCRIBED AND SWORN TO under my hand and seal  
of office on this the \_\_\_\_\_ day of  
\_\_\_\_\_, \_\_\_\_\_.

\_\_\_\_\_  
Rebecca J. Callow, RMR, CRR, RPR  
Notary Public, Travis County, Texas  
My Commission No. 12955701-3  
Expires: 09/12/2017

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